UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/937,756	09/25/1997	DAVID C. RUEGER	JJJ-P06-504	2132

7590 07/07/2004

Erika Takeuchi
ROPES & GRAY LLP
45 Rockefeller Plaza
New York, NY 10111-0087

EXAMINER	
TURNER, SHARON L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/937,756	RUEGER ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97,99 and 105-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97,99 and 105-111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The amendment filed 4-12-04 has been entered into the record and has been fully considered.

2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

3. As a result of Applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

4. Claims 97, 99 and 105-111 are pending.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 97, 99 and 105-111 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,194,376. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to a species of decreasing neuronal cell death associated with neuropathy and/or chemical or physical

injury which anticipates the instantly claimed genus. The species is of immune cell mediated inflammatory response in ischemia reperfusion or hyperoxia injury in neurons as noted in claims 1, 4, 5 and 6. The treatments each provide for administration in contact with the same morphogenic compounds and the same neuronal cells. Thus, the '376 claims render obvious instant claims.

7. Claims 97, 99 and 105-111 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,723,698. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to a species of decreasing neuronal cell death associated with neuropathy and/or chemical or physical injury which anticipates the instantly claimed genus. The species is of a mammal with amyotrophic lateral sclerosis in which patients are afflicted with motor neuron degeneration or neuropathy and physical injury and to mammals with symptoms of spinal cord injury encompassed as a patient with a chemical or physical injury. Also included is a method of repairing damaged neural pathways and improving neural function as in claims 14-15. The treatments each provide for administration in contact with the same morphogenic compounds and the same neuronal cells, see in particular claims 1-2, 3 and 5 in particular. Thus, the '376 claims render obvious instant claims.

8. Claims 97, 99 and 105-111 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,506,729. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to a species of

decreasing neuronal cell death associated with neuropathy and/or chemical or physical injury which anticipates the instantly claimed genus. The species is of treating a mammal with symptoms of Parkinsons diseases wherein motor function is restored. In particular Parkinsons is a disease of neuropathy or neuronal cell death induced by chemical or physical trauma. The treatments each provide for administration in contact with the same morphogenic compounds and the same neuronal cells, see in particular claims 1-2, 3 and 6 in particular. Thus, the '729 claims render obvious instant claims.

9. Claims 97, 99 and 105-111 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,288,031. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to a species of decreasing neuronal cell death associated with neuropathy and/or chemical or physical injury which anticipates the instantly claimed genus. The species is of reducing an inflammatory response in a patient with neural tissue damage which is recognized as providing for decreased neuronal cell death as in ischemic-repurfusion tissue injury, hypoxic tissue injury and hyperoxic tissue injury as in claim 4. The tissue is of neural tissue as in claim 6. Also noted are the neurodegenerative diseases as in claim 7. The treatments each provide for administration in contact with the same morphogenic compounds and the same neuronal cells, see in particular claims 1-3. Thus, the '031 claims render obvious instant claims.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 97, 99 and 105-111 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enhancing neuronal cell survival (decreasing neuronal cell death) as provided for in the specification at p. 70-72, does not reasonably provide enablement for such action via stimulation of N-CAM or L1 in neuronal cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

Applicants claims are directed to a method for decreasing neuronal cell death associated with neuropathy, chemical and physical injury. The claims recite wherein the contacting is of the neuronal cell with the morphogens recited wherein the "morphogen stimulates the production of an N-CAM or L1 isoform in said neuronal cells." While the specification teaches that the noted morphogens provide for N-CAM or L1 expression, the specification does not provide any evidence that this expression is correlated, related to or predictive of providing for decreased neuronal cell death or for promoting neuronal survival as in the cultures noted at pp. 70-72. The cultures do not evidence

that the expression of N-CAM/L1 is demonstrative of survival or decreased neuronal cell death. Because the preamble of the claims is not provided by the claimed method, the claim is deemed non-enabling for its full scope. The Examiner further notes that a search of the primary literature fails to reveal any evidence that N-CAM/L! expression is related to neuronal cell survival or decreased neuronal cell death.

The specification does not enable the broad scope of the claims which encompasses a multitude of analogs or equivalents because the specification does not teach how N-CAM/L1 expression would be expected to provide for neuronal cell survival or decreased neuronal cell death. Survival of neuronal cells is not evidenced to be dependent on N-CAM/L1 expression, see in particular Lein et al., 1995 of record, Le Roux et al., 1999, and Bengtsson et al., 1998. The specification provides essentially no guidance as to which of the essentially infinite possible choices is likely to be successful. In particular, the morphogens recited differ substantially in structure.

Thus, applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled artisan cannot readily make and use the claimed invention without further undue experimentation.

Status of Claims

12. No claims are allowed.

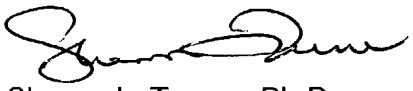
13. Applicants are reminded of their duty to disclose. The Examiner notes multiple co-pending applications via instant Inventors, the status of which may change during prosecution on the merits.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.



Sharon L. Turner, Ph.D.
June 17, 2004